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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,891	01/28/2000	Wallace A. Longton	LEH-35B-98	2793

7590 10/20/2004

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EXAMINER	
MAIER, LEIGH C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/493,891	LONGTON ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-15* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claim 4 is canceled. Claim 15 is newly submitted. Claims 3 and 6-9 have been amended. Claims 1-3 and 5-15 are pending. Claims 1, 2, and 10-14 are withdrawn as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objection or rejection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 3 has been amended to require dehydration "for a period of greater than 5 hours." The examiner does not find support for this new limitation.

Claim Rejections - 35 USC § 102

Claim 9 is again rejected under 35 U.S.C. 102(b) as being anticipated by HEINDEL et al (Bioconjugate Chem., 1994), as set forth in the previous Office action.

Applicant's arguments filed July 21, 2003 have been fully considered but they are not persuasive.

Applicant has amended to process to distinguish it from that disclosed in the reference. However, Applicant fails to indicate how the product formed differs from the product-by-process of claim 9. The rejection is maintained for reasons of record.

Claim 9 is again rejected under 35 U.S.C. 102(b) as being anticipated by AKANUMA et al (J. Biochem., 1978), as set forth in the previous Office action.

Applicant's arguments filed July 21, 2003 have been fully considered but they are not persuasive.

Applicant contends that other references have reported that the reagents used in the reference process remain trapped by covalent adduct formation. However, these references are not currently before the examiner for consideration.

Applicant further notes that AKANUMA employs crosslinked polysaccharides "unlike the non-crosslinked polysaccharides of the present invention." The claim does not preclude the use of crosslinked polysaccharides.

Claim 9 is again rejected under 35 U.S.C. 102(a) as being anticipated by MARTEY et al (CAPLUS abstract 1998:529836, 1998), as set forth in the previous Office action.

Applicant's arguments filed July 21, 2003 have been fully considered but they are not persuasive.

It appears that Applicant is arguing that this reference is a description of proposed work that was never actually completed, stating "no results from either cellulose or *any other carbohydrates* were in hand." (Emphasis added) This is not persuasive in view of what was known from HEINDEL (the reference discussed above), considering that the first author on that reference is also an author on the MARTEY reference.

Claim Rejections - 35 USC § 103

Claims 3 and 9 are again rejected under 35 U.S.C. 103(a) as being unpatentable over AKANUMA et al (J. Biochem., 1978), as set forth in the previous Office action. Newly added claim 15 is included in this rejection.

Applicant's arguments filed July 21, 2003 have been fully considered but they are not persuasive.

Applicant contends that the reference does not employ heating in the lactonization step. However, the claim recites "thermal dehydration" but does not require any particular temperature, and the specification does not have any particular definition of "thermal dehydration."

Applicant argues that this process would yield an unacceptably high level of impurities. Although Applicant presents no evidence to support this argument, it is not germane to the rejection because the claims have no particular purity requirement.

Applicant further argues that there is no expectation that a method suitable for producing a chromatography platform would be appropriate for using on a pharmaceutical carrier. Again, Applicant is basing arguments on limitations not present in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 3, 5, 6, and 9 are again rejected under 35 U.S.C. 103(a) as being unpatentable over HEINDEL et al (Bioconjugate Chem., 1994) and AKANUMA et al (J. Biochem., 1978), as set forth in the previous Office action. Newly added claim 15 is included in this rejection.

Applicant's arguments filed July 21, 2003 have been fully considered but they are not persuasive.

Applicant argues that cellulose does not lactonize under the same conditions that can be used with CM-dextran and that structural differences between the compound preclude the use of the HEINDEL for use with CM-cellulose. This is not found persuasive because Akanuma had demonstrated that CM-cellulose is capable of undergoing lactonization. One of ordinary skill would be aware of possible variability in reactivity among polysaccharides. However, Heindel had clearly taught a method of monitoring the reaction by IR analysis. It would be within the scope of the artisan to monitor the reaction as directed and adjust the reaction time accordingly.

Claims 3 and 5-9 are again rejected under 35 U.S.C. 103(a) as being unpatentable over HEINDEL et al (Bioconjugate Chem., 1994) and AKANUMA et al (J. Biochem., 1978) in

further view of MILL et al (US 4,003,792), as set forth in the previous Office action. Newly added claim 15 is included in this rejection.

Applicant's arguments filed July 21, 2003 have been fully considered but they are not persuasive.

Applicant points to differences in flexibility among various polysaccharides and that dextran is the most flexible. It appears that Applicant's argument here is that the other polysaccharides would be less likely to undergo lactonization. That may be, but as noted above, Akanuma has demonstrated that CM-cellulose does indeed undergo lactonization.

Applicant goes on to contrast various physical properties of dextran and cellulose. This comparison is particularly irrelevant as neither of these, *per se*, is a substrate for this reaction. The examiner fails to find any relevance in the respective colors of CM-dextran and CM-cellulose.

Finally, Applicant goes on to discuss conditions for ring opening and fragrance/pharmaceutical attachment, but the claims have no such limitation.

Claims 3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEINDEL et al (Bioconjugate Chem., 1994) and HALL et al (US 4,424,346).

Heindel teaches as set forth in the previous Office action. Heindel does not exemplify the full scope of polysaccharides recited in claim 15.

Hall teaches the preparation of conjugates of chitosan derivatives, including N-carboxymethyl chitosan. See abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method taught by Heindel to prepare a chitosan lactone as an intermediate for the art-disclosed utility in preparing conjugates. One of ordinary skill would reasonably expect success in using this method with a chitosan substrate.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

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JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Leigh C. Maier
Patent Examiner
October 15, 2004